

Patient Information

1. Identifier [REDACTED]	2. Age at time of event: or UNK Date of Birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or kgs
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In confidence

B. Adverse event or product problem

- 1.
- ☒
- Adverse event
- ☐
- Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☒ death (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization—initial or prolonged
- ☐ recovered

- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr) UNK 4. Date of this report (mo/day/yr) 10/26/2000

5. Describe event or problem

Information was received on 14-FEB-2000 from an Attorney concerning a female patient (age unknown) who received METHOTREXATE (Injection) for Rheumatoid arthritis. The dose regimen was 25mg once weekly "for a fair period of time". Medical history was not provided. The patient was admitted to a hospital for an unspecified surgery. During the hospitalization, a single 50mg dose of methotrexate was administered to the patient. Shortly thereafter, the patient died. According to the reporter, the plaintiff alleges that methotrexate in combination with acetaminophen and isoflurane "created a deadly synergistic effect"; the reporter implied that cause of death was hepatotoxicity.

6. Relevant tests/laboratory data, including dates
None Provided.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CONCURRENT CONDITIONS:

Rheumatoid arthritis

PAST CONDITIONS:

Operation NOS

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeled, if known)

#1 METHOTREXATE (METHOTREXATE, Injection)

#2 ACETAMINOPHEN (PARACETAMOL,) (cont'd)

2. Dose, frequency & route used

#1 25 mg 1x per 1 Wk

#2 UNK

3. Therapy dates (if unknown, give duration)

#1 "For a fair period of time" Continues

#2 UNK

4. Diagnosis for use (indication)

#1 Rheumatoid arthritis

#2 UNK

5. Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☒ doesn't apply#2 ☐ yes ☐ no ☒ doesn't apply

6. Lot # (if known)

#1

#2

7. Exp date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply#2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. All manufacturers

1. Contact office - name/address

LEDERLE LABS (RA)
240 N Radnor-Chester
St. Davids, PA 19087

Jill Robinson

2. Phone number

6109024647

3. Report source (check all that apply)

- ☐ foreign
- ☐ study
- ☐ literature
- ☒ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr)

02/14/2000

6. If IND, protocol #

7. Type of report

☐ 5-day ☐ 15-day☐ 10-day ☒ periodic☒ Initial ☐ follow-up #

9. Mfr. report number

HQ1110617FEB2000

5. (A)NDA 11-719

IND #

PLA #

pre-1938 ☐ yesOTC product ☐ yes

8. Adverse event term(s)

Hepatotoxicity NOS

Overdose NOS

Drug interaction NOS

E. Initial reporter

1. Name & address

phone #

OCT 20 2000

2. Health professional?

☐ yes ☒ no

3. Occupation

4. Initial reporter also sent report to FDA

☐ yes ☐ no ☒ unk



3667671-0-00-02

EDWATCH

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ1110617FEB2000

UF/Dist report #

FDA Use Only

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1. Suspect medication(s) (Continuation)

Name (give labeled strength & mfr/labeler, if known)

- # 1.2 METHOTREXATE (METHOTREXATE, Injection)
- # 3.1 ISOFLURANE (ISOFLURANE,)

2. Dose, frequency & route used

- # 1.2 50 mg 1x per 1 Dos
- # 3.1 UNK

3. Therapy dates (if unknown, give duration)

- # 1.2 UNK
- # 3.1 UNK

4. Diagnosis for use (indication)

- # 3.1 Anaesthesia NOS

5. Event abated after use stopped or dose reduced

- # 3.1 DOESN'T APPLY

6. Lot # (if known)

- # 3.1

7. Exp date (if known)

8. Event reappeared after reintroduction

- 3.1 DOESN'T APPLY

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